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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,037	11/25/2005	Paul Heeres	294-219 PCT/US	1310
23869	7590	10/03/2008	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791				ROBINSON, KEITH O NEAL
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,037	HEERES ET AL.	
	Examiner	Art Unit	
	KEITH O. ROBINSON	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 June 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-14 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 01 June 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/6/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 112, second paragraph

1. Claim 14 provides for the use of a potato plant or part derived thereof having at least one *amf* allele in a breeding and selection program, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to any potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m.

It appears that the claimed plant is a product of nature because it is broadly drawn to any potato having the claimed characteristics, wherein said plant may occur naturally, without the requirement of manipulation by the hand of man. Poehlman et al (Breeding Field Crops, 4th ed., 1995) teach that spontaneous mutations can occur in nature and that there is no clear distinction between spontaneous mutations and induced mutations (see page 108). Accordingly, the claimed plant would possess the same characteristics and utility as those found naturally and therefore do not constitute patentable subject matter.

In addition, the instant claims do not denote the hand of man in the claimed invention. See MPEP 2105 and *Diamond v. Chakrabarty*, 206, USPQ 193 (1980) at 197 that states that “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter”. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948).

Claim Rejections - 35 USC § 112, first paragraph – Written Description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn to any potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m and methods of breeding and using said potato plant.

MPEP 2163(I) states “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116”.

The specification does not provide any description of any potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m nor is there any description of said potato plant having the additional characteristics claimed in claims 2-9, methods for breeding said potato as claimed in claims 10-12, a potato produced from said methods as claimed in claim 13 and use of said potato as claimed in claim 14 in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

MPEP 2163.02 states, “[u]nder Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art

that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed".

In the instant case, Applicant has not conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, that Applicant was in possession of the claimed invention because the specification fails to provide any evidence of the claimed.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

6. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broadly drawn to any potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m and methods of breeding and using said potato plant.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification fails to provide any guidance regarding any potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m and methods of breeding and using said potato plant; thus, one skilled in the art would not be able to make and use the claimed invention.

The specification fails to provide any working examples of any potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m and methods of breeding and using said potato plant.

Thus, based on the lack of guidance regarding a potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m and methods of breeding and using said potato plant, the lack of working examples of a potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m and methods of breeding and using said potato plant and the breadth of the claims, it would require undue trial and error experimentation to make and use the claimed invention.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jacobsen et al (Euphytica 44: 43-48, 1989).

The claims read on a potato plant having at least one *amf* gene said potato plant further provided with an increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m and methods of breeding said potato plant.

Jacobsen et al teach a potato plant having at least one *amf* gene (see, for example, page 44, 'Materials and methods' where it teaches monoploid amylose-free (*amf*) clone '86.040'). Jacobsen et al is silent regarding increased capacity to store a protein as characterized by a protein content of its tubers of at least 1.9% m/m; however, it would be obvious to one of ordinary skill in the art that increased capacity to store a protein would be important in potatoes and that a protein content of at least 1.9% is a design choice that would vary depending of the individual goals of the breeder.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

In addition, Jacobsen et al teach a method for breeding and selecting a potato plant comprising crossing a first parent potato with at least one *amf*-gene with a second parent potato without an *amf*-gene and selecting progeny (see, for example, page 47, 1st column, last paragraph where it teaches the cross of '86.040' (which is the *amf* clone) x wildtype. It also teaches that the mutant character is recessive and monogenic; thus, one skilled in the art would easily be able to select progeny).

Conclusion

10. No claims allowed.

Contact Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 7:30 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.
Examiner
Art Unit 1638

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638

September 21, 2008